

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN COLLEGE OF
OBSTETRICIANS AND
GYNECOLOGISTS, *on behalf of its members
and members' patients*,
COUNCIL OF UNIVERSITY CHAIRS OF
OBSTETRICS AND GYNECOLOGY, *on
behalf of its members and members' patients*,
NEW YORK STATE ACADEMY OF
FAMILY PHYSICIANS, *on behalf of its
members and members' patients*,
SISTERSONG WOMEN OF COLOR
REPRODUCTIVE JUSTICE COLLECTIVE,
*on behalf of its members and members'
patients*, and
HONOR MACNAUGHTON, M.D.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,
STEPHEN M. HAHN, M.D., *in his official
capacity as Commissioner of Food and Drugs,
and his employees, agents and successors in
office*,
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES and
ALEX AZAR, J.D., *in his official capacity as
Secretary, United States Department of
Health and Human Services, and his
employees, agents and successors in office*,

Defendants.

Civil Action No. TDC-20-1320

PRELIMINARY INJUNCTION

For the reasons set forth in the accompanying Memorandum Opinion and Order, it is
hereby ORDERED that:

1. Defendants United States Food and Drug Administration (“FDA”), FDA Commissioner Stephen M. Hahn, the United States Department of Health and Human Services (“HHS”), and Secretary of Health and Human Services Alex Azar (“the Secretary”); Defendants’ agents, employees, appointees, or successors; and all other persons who are in active concert and participation with them, are ENJOINED from enforcing, threatening to enforce, or otherwise applying the following provisions of the “Elements to Assure Safe Use” (“ETASU”), 21 U.S.C. § 355-1(f)(3) (2018), set forth in the mifepristone Risk Evaluation and Mitigation Strategy (“REMS”), ECF No. 1-4, as to the dispensing of mifepristone for use as part of a medication abortion regimen, against Plaintiffs, their members, other similarly situated individuals or entities, and other individuals or entities involved in implementing the injunctive relief, without geographic limitation:

- a. ETASU C, 21 U.S.C. § 355-1(f)(3)(C), only to the extent that it requires that mifepristone may be dispensed only in clinics, medical offices, or hospitals, rather than by mail or delivery service. Dispensing by mail or delivery service must still occur by or under the supervision of a certified healthcare provider as defined in the REMS.
- b. ETASU D, 21 U.S.C. § 355-1(f)(3)(D), only to the extent that it: (1) requires patients obtaining mifepristone to sign the Patient Agreement Form in the physical presence of a certified healthcare provider, rather than by signing it physically or electronically during a telemedicine session with a certified healthcare provider and promptly returning the form electronically or by mail, or by giving oral assent to its terms during such a session that the healthcare provider then documents in the patient’s record; and (2) requires the certified healthcare provider to present the patient with a copy of the form at a clinic, medical office, or hospital, rather than promptly providing a copy of the form electronically or by mail.
- c. ETASU A, 21 U.S.C. § 355-1(f)(3)(A), only to the extent that it requires certified healthcare providers seeking to prescribe mifepristone to attest that they will: (1) obtain the patient’s physical signature on the Patient Agreement Form, rather than obtaining a physical or electronic signature during a telemedicine session with a certified healthcare provider and promptly

receiving a copy of the signed form electronically or by mail, or by obtaining oral assent to its terms during such a session that the healthcare provider then documents in the patient's record; (2) present the patient with a copy of the form at a clinic, medical office, or hospital, rather than promptly providing a copy of the form electronically or by mail; and (3) place in the patient's medical record a copy of the form containing the patient's physical signature, rather than placing a copy of the form signed electronically during a telemedicine session with a certified healthcare provider or documenting the patient's oral assent to its terms in the patient's record.

2. The preliminary injunction shall extend until 30 days after the end of the Public Health Emergency declared by the Secretary pursuant to 42 U.S.C. § 247d(a) associated with or related to SARS-CoV-2 transmission and the illness known as COVID-19, including the periods of any subsequent renewals of the declaration.
3. If the Public Health Emergency ends during the pendency of this case, Plaintiffs may file a motion to extend the preliminary injunction based on specific evidence, to be presented with that motion, that demonstrates an ongoing public health justification for the continuation of the preliminary injunction.
4. Pursuant to Federal Rule of Civil Procedure 65(c), Plaintiffs are required to post with this Court a bond of \$1,000.
5. The preliminary injunction shall take effect upon the posting of the bond.

Violations of this Order shall subject Defendants and all other persons bound by this Order to all applicable penalties, including contempt of court.

Date: July 13, 2020

/s/ Theodore D. Chuang
THEODORE D. CHUANG
United States District Judge